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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,067	12/13/2004	Carsten Pilger	MG-2519	2721

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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/518,067	PILGER ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/18/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,7 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,7 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of remarks filed on 4/4/2006 and on 5/18/2006. Applicant's arguments have been carefully considered but are not found to be persuasive for the reasons of record and those stated below. Upon further consideration, the Examiner has a new ground of rejection. This action is non-final. Applicant has cancelled claims 1, 5, 6, 8 and 12-14. Claims 2-4, 7 and 9-11 are pending in the application.

Withdrawn rejections:

Claims 2-4, 7 and 9-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Lecourt et al. (US 2002/0033174). Applicant has amended the claims and the reference of Lecourt et al. is deemed not to anticipate the instantly claimed method and the Examiner withdraws the rejection.

Claims 2, 7 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Georgieff (US 6,197,323). Applicant has cancelled claims and amended the claims such that the reference of Georgieff is deemed not to anticipate the instantly claimed method and the Examiner withdraws the rejection.

Claims 2, 7 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Franks et al. (WO 00/76545). Applicant has cancelled claims and amended the claims such that the reference of Franks et al. is deemed not to anticipate the instantly claimed method and the Examiner withdraws the rejection.

Claims 1, 3 and 12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-27 and 32 of copending

Application No. 10/380,869. Cancellation of claims 1, 3 and 12 and cancellation of claims 1-44 of the copending application make the rejection moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4, 7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of stroke, does not reasonably provide enablement for prophylaxis of stroke. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, a method of treating stroke. However, Applicant is purporting to prophylaxis of stroke, which the Examiner interprets to mean prevention of stroke.

2) Nature of the invention

The nature of the invention is directed to a method of treating a patient with a xenon adjuvant and a medicament.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that stroke can be indicated by a sudden development of a number of symptoms including weakness or paralysis, slurred speech and mood changes (Medical Encyclopedia: stroke, page 2, symptoms). Stroke is a medical emergency and requires immediate treatment (Medical Encyclopedia: stroke, page 3, treatment).

5) Level or degree of predictability, or a lack thereof, in the art

A high degree of unpredictability existed in the state of the prior art regarding the prevention of stroke. The art teaches to help prevent a stroke lifestyle changes such as proper maintenance of blood pressure and cholesterol levels, cessation of smoking and loss of weight

but does not indicate any method to positively prevent a stroke (Medical Encyclopedia: stroke, page 5, Prevention).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a method for treating stroke, it does not provide sufficient guidance on the prevention of stroke.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a method of preventing stroke.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to perform expensive and time consuming animal model studies to first ascertain if the instantly claimed method would prevent a stroke. Then one of ordinary skill in the art would have to test the method in clinical trials with human patients knowing that the failure of the method could result in patient death. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to safely, reasonably and accurately determine whether the method of the instant application does in fact prevent stroke.

Claim Rejections - 35 USC § 112

Claims 2-4, 7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In the instant case, the invention is drawn to a method of treating a patient with a composition comprising xenon and a medicament wherein xenon is an adjuvant. The instant specification defines adjuvant as "means assisting the effect of a medicament are referred to in medicine as adjuvant" (page 1, lines 23-24). Applicant supplied a laundry list of medicaments and classes of medicaments (see claims 7 and 9) to be used in the invention without providing any evidence that xenon, in the disclosed amounts, can act to assist the effect of the medicament.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims recite a plurality of conditions from chronic neurodegenerative disorders to acute and chronic cerebral disorders or impairments to something as broad as "the sequelae of a cerebral ischemia" (Claims 7 and 9). The specification merely discloses, without more, a general

method of treating a patient first with xenon and then with a medicament without providing dosages, duration, or expected endpoints for the treatment (page 7, lines 20-24).

2) Nature of the invention

The nature of the invention is directed to a method of treating a patient with a xenon adjuvant and a medicament.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that xenon can be used as an anesthetic gas (US 5,228,434).

5) Level or degree of predictability, or a lack thereof, in the art

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. The instant specification provides no guidance for one of ordinary skill in the art to determine when xenon is acting as an adjuvant with the medicament for the treatment of the claimed conditions. How is one of ordinary skill in the art able to determine if it is merely the medicament doing its job or if the medicament has enhanced efficacy due to the adjuvant xenon?

7) Presence or absence of working examples

The specification fails to provide any scientific data and any working embodiments with respect to a method of treating a patient with xenon as an adjuvant and a medicament.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to perform expensive and time consuming animal model studies with each and every combination of xenon and medicament (which represents thousands of drugs) to first ascertain if the instantly claimed method would work in the manner instantly claimed and then analyze the data against positive controls to see if xenon assisted the effect of the administered medicament. Then one of ordinary skill in the art would have to test the method in clinical trials with human patients knowing that the failure of the method could result in patient death. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to safely, reasonably and accurately determine whether the method of the instant application is in fact enabled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 7 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites: "what is administered". The Examiner requires clarification on exactly what is "what". Furthermore, it is confusing to the Examiner

with respect to "condition". Claim 7 recites "the medicament is active for treating a condition" and then lists medicaments selected from the group consisting of, for example, diagnostic aids, x-ray contrast agents etc... What condition is a diagnostic aid treating? Furthermore, which of the medicaments of claim 7 correspond to the method of claim 9?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4 and 7 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Fishman (US 5,228,434).

Fishman disclose a mixture consisting of from 60 to 78.5 mole percent stable xenon, from 19.5 to 38 mole percent oxygen and from 2.5 to 20.5 mole percent helium (Claim 1). Methods of making and methods of using the gas mixture are disclosed (Column 3, lines 14-42 and column 5, lines 8-36) and use of the gas mixture in combination with intravenously introduced methyl-atrophine bromide, thiopentone and fentanyl (Column 5, lines 10-13). In addition to these therapeutic agents, the Examiner interprets oxygen as a therapeutic active ingredient (a migraine remedy) that will enter the bloodstream. The mixture is administered to the patient by a re-breathing system and therefore reads on instant claim 4 (Column 5, lines 19-26 and claim 4).

Response to arguments:

Applicant asserted that xenon is an adjuvant in the composition and in the disclosure of Fishman xenon is acting as an anesthetic. The Examiner directs Applicant to two facts: 1) instant claim 7 recites "whereby what is administered to the patient contains no more than 70% by volume xenon" and " the combined gas supplied to the patient contains from 5 to 70% by volume xenon" and 2) A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Fishman disclose a composition comprising 70% xenon thus meeting the instantly claimed limitation cited above (Column 5, lines 17-18). The patient disclosed by Fishman is undergoing surgery, which the Examiner interprets to be a condition, and a medicament, for example the analgesic fentanyl is co-administered with the xenon containing gas mixture (Column 5, lines 8-13). Instant claim 7 recites "analgesically or anesthetically acting substance" which the Examiner interprets to include fentanyl. Thus, the disclosure of Fishman reads upon the instantly claimed invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 7 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of copending Application No. 10/517,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 7 and 9 are embraced by the copending claims 7 and 9.

The copending application teaches a method of treating a patient with xenon or a xenon containing gas mixture in a subanesthetic amount of xenon wherein what is administered to the patient contains no more than 70% by volume of xenon for the treatment of spasms, vasospasms, cerebral vasospasms, improvements of blood flow, impairments of blood flow in the brain, cognitive impairments, stroke etc...selecting as a patient someone having such condition and administering the xenon medicament to the patient (Claim 7). The copending application teaches the inclusion of an NO source (Claim 9). The Examiner interprets NO to be an antibacterial agent as well as a substance that influences blood clotting.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the copending application embraces the instant claims by having a method with

xenon in the exact same proportions and a medicament, NO, for the treatment of, for example, impairments of blood flow in the brain. One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application based on the overlapping scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claims 7 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5, 6, 7 and 9 of copending Application No. 10/517,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims.

The copending application teaches a method of treating a patient with xenon or a xenon containing gas mixture in a subanesthetic amount of xenon wherein what is administered to the patient contains no more than 70% by volume of xenon for the treatment of, for example impairments of blood flow in the brain and cognitive dysfunction, selecting as a patient someone having such condition and administering the xenon medicament to the patient (Claims 6 and 7). The copending application teaches the inclusion of an NO source (Claims 5 and 9). The Examiner interprets NO to be an antibacterial agent as well as a substance that influences blood clotting.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the copending application embraces the instant claims by having a method with xenon in the exact same proportions and a medicament, NO, for the treatment of, for example,

impairments of blood flow in the brain. One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application based on the overlapping scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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